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K101565
SEP 20 2010

Official Contact: CY Wang – RD VP
Atlantean
1F, No. 789, Bo-ai Street
Chubay City, TAIWAN
Tel - 886-3-555-8340
Fax - 886-2-2736-3250

Proprietary or Trade Name: SB100II Finger Pulse Oximeter

Common/Usual Name: Pulse oximeter

Classification Name: Oximeter
DQA – 870.2700

Predicate Devices: Contec Medical Systems, K082641, CMS-50DL
Smith's Medical, K013171, BCI3420

Device Description:
The SB100II pulse oximeter is an instrument for photoelectrically determining the oxygenation of blood in a translucent part of the body, in this case the finger.

This SB100II contains the electronics to interface to the integral sensor. This sensor consists of a light emitting diode and a photoelectric cell placed on either side of the finger. Red and infrared light are transmitted through oxyhemoglobin and are sensed in the photoelectric cell. The red and infrared light is absorbed in different amounts depending on the oxygenation of the blood.

The SB100II has the ability to determine both the percent of saturated hemoglobin and the pulse rate. It performs these functions on adult and pediatric patient populations. It is designed for spot checking both the SpO_2 and Pulse rate information. To perform this, the SB100II display digital values for both the SpO_2 and Pulse.

Pulse amplitude is displayed graphically by means of a vertical bar, which elevates in synch with the pulse cycle. The SB100II is powered by two "AAA" batteries. The wavelength of red LED is 660nm and Infrared LED is 905/880nm with maximum optical output power of 4mW.

The device incorporates a battery state indicator and provides a visual indication of low battery.

Summary Description:

- The SB100II is not life-supporting or life-sustaining, not for implant.
- The SB100II is not sterile
- The SB100II is reusable.
- The SB100II is for prescription use.
- The SB100II does not contain drug or biological products
- The SB100II is a class II device, product code DQA regulation 21 CFR 870.2700.

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- The SB100II is a standalone device it is not part of a multi-parameter module and does not connect to any other devices
- The SB100II is for use in spot-checking it is not intended for continuous monitoring.
- The SB100II is not intended for out of hospital transport
- The SB100II can be used in homes.
- The SB100II is a transmittance device that calculates functional SpO_2.
- The SB100II does not provide audio or visual alarms
- The SB100II has only one control - the On / Off key. When the device is on it can display the following:
    - SpO_2 values
    - Pulse Rate
    - An indication of pulse amplitude.
- There are no accessories for use with the SB100II. The sensor is integral to the device and is spring loaded so that it does not need to be adhered to the skin by tape or other measures.
- The SB100II is a standalone device that does not interface to any other devices so there are no patient cables, extender cables, sensors or external power supplies.
- The SB100II is not provided sterile is not intended to be sterilized.
- The SB100II is not a reprocessed device.
- The SB100II does not have multiple modes. It is on or off, when it is on, it measures SpO2 and pulse rate as described above.
- There are no claims relative to motion tolerance
- There are no claims relative to low perfusion

Indications for Use:
The SB100II Fingertip Pulse Oximeter is a non-invasive device intended for the spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). The SB100II is not intended for continuous monitoring.

Patient Population:
Adult and pediatric patient populations

Environment of Use:
Home and hospital

Contraindications:
None

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Attribute	Smiths Medical BCI3420 510(k) K013171	Contec Medical Systems CMS50 DL 510(k) K082641	Atlantean SB100II (This submission)	Discussion of Differences
Indications for Use	The BCI 3420 Digit Pulse Oximeter is a handheld, finger mounted pulse oximeter that combines the monitor and sensor into one assembly that measures SpO_2, pulse rate and pulse strength. It may be used as a spot check device in the home, hospital or clinical environments, including patient ground transport in clinical and EMS (Emergency Medical Services) settings. The BCI 3420 Digit Pulse Oximeter will provide reliable measurements on patient ranging from pediatric to adults.	The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). This device is not intended for continuous monitoring.	The SB100II Fingertip Pulse Oximeter is a non-invasive device intended for the spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist / surgery, anesthesia, intensive care etc.). The SB100II is not intended for continuous monitoring.	Same as K082641
Environments of use	home, hospital or clinical environments, including patient ground transport in clinical and EMS (Emergency Medical Services) settings	home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.	home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.	Same as K082641
Intended application site	Finger	Finger	Finger	Same
Low perfusion claims	No	No	No	Same
Motion Claims	No	No	No	Same
Prescriptive	Yes	Yes	Yes	Same as K082641
Patient population	Pediatric / adult	Pediatric / adult	Pediatric / adult	Same
Reusable	Yes	Yes	Yes	Same
Display Type	LED	LED	LED	Same

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Attribute	Smiths Medical BCI3420 510(k) K013171	Contec Medical Systems CMS50 DL 510(k) K082641	Atlantean SB100II (This submission)	Discussion of Differences
Display Parameter	SpO2, Pulse Rate, Pulse Strength	SpO2, Pulse Rate, Pulse Strength	SpO2, Pulse Rate, Pulse Strength	Same
Controls	On	On	On / off	Same
Alarms	Unknown	Unknown	None	No alarms on SB100II
SpO2				
Range	0-99%	35-99%	35-99%	Same as K082641
Resolution	1%	1%	1%	Same
Accuracy	+/-2% 70-99%	+/-2% 70-99%	+/-3% 70-99%	Similar, actual Arms 2.5 Meets FDA guidance for non-motion ≤ 3.0 % Meets ISO 9919 for non-motion ≤ 4.0 %
	<70% unspecified	<70% unspecified	35-69% unspecified	Same as K082641
Type	Functional	Not specified	Functional	Same
Pulse				
Range	30-254 bpm	30-250 bpm	30- 250 bpm	Same as K082641
Accuracy	±2% or 2 bpm whichever is greater	±2% or 2 bpm whichever is greater	±3 bpm	Similar
Resolution	1 bpm	1 bpm	1 bpm	Same
Power	2 "AAA" batteries	2 "AAA" batteries	2 "AAA" batteries	Same
Battery Life	16 hours continuous 1400 spot checks	30 hours	16 hours continuous	Same time duration as K013171

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Attribute	Smiths Medical BCI3420 510(k) K013171	Contec Medical Systems CMS50 DL 510(k) K082641	Atlantean SB100II (This submission)	Discussion of Difference
Environmental				
Dimensions	57.2 x 43.3 x 38.1 mm	unknown	63.5x34x35mm	Similar to K013171
Weight	85g	Unknown	37g	Lighter than K013171
Operating Temperature	10°C--55°C	Unknown	5°C to 40°C	Similar to K013171
Storage Temperature	-40°C-75°C	Unknown	-20°C to 70°C	Similar toKk013171
Operating Humidity	15%-95%	Unknown	15%-95%	Similar to K013171
Storage Humidity	10-95%	unknown	15%-95%	Similar to K013171
Standards				
IEC 60601-1	Yes (undated)	Yes (undated)	Yes IEC 60601-1: 1988 +A1+A2	SB100II meets current revision of the recognized consensus standard
IEC 60601-1-2	Yes EN 60601-1-2: 1993	Yes (undated)	IEC 60601-1-2: 2001 +A1	SB100II meets current recognized consensus standard
ISO 9919	Unknown	ISO 9919: 2005	ISO 9919: 2005	Same as k082641 (current revision of the recognized consensus standard)
General				
Protection against ingress of water	Unknown	Unknown	IPX1 and ISO 9919 Clause 44	Meets FDA guidance
Protection Class (electrical safety)	Unknown	Unknown	Type BF	Protection class is suitable for application per IEC 60601-1

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Performance Testing:

The following performance tests were done and the SB100II meet all requirements.

- ISO 9919 including clinical testing
- IEC 60601-1-2
- IEC 60601-1

Substantial Equivalence:

The SB100II Pulse Oximeter is viewed as substantially equivalent to the predicate devices because it performs the same basic functionality by similar technical means.

Indications –
The SB100II Fingertip Pulse Oximeter is a non-invasive device intended for the spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). The SB100II is not intended for continuous monitoring.

Technology –
The SB100II pulse oximeter is an instrument for photoelectrically determining the oxygenation of blood in a translucent part of the body, in this case the finger.

This SB100II contains the electronics to interface to the integral sensor. This sensor consists of a light emitting diode and a photoelectric cell placed on either side of the finger. Red and infrared light are transmitted through oxyhemoglobin and are sensed in the photoelectric cell. The red and infrared light is absorbed in different amounts depending on the oxygenation of the blood.

Materials –
The materials in contact with the patient as common to medical devices.

Environment of Use –
Home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.).

Patient Population –
Adult and pediatric

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Atlantean
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

SEP 20 2010

Re: K101568
Trade/Device Name: SB100II Finger Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 15, 2010
Received: September 16, 2010

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

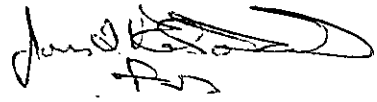
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

K101568

510(k) Number: _____ (To be assigned)

Device Name: **SB100II Finger Pulse Oximeter**

SEP 20 2010

Indications for Use:

The SB100II Fingertip Pulse Oximeter is a non-invasive device intended for the spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). The SB100II is not intended for continuous monitoring.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101568